WIRELESS MEDICAL SENSORS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Patent Application Nos. 62/710,324 filed Feb. 16, 2018, 62/631,692 filed Feb. 17, 2018, and 62/753,203 filed Oct. 31, 2018, each of which is specifically incorporated by reference to the extent not inconsistent herewith.

BACKGROUND OF INVENTION

[0002] Provided herein are medical sensors, including mechano-acoustic sensing electronics, coupled with onboard microphone and feedback stimuli, including but not limited to vibration motor, speaker, or LED indicator. Systems and methods are provided for mechano-acoustic electrophysiological sensing electronics derived from the body using a 3-axis high frequency accelerometer. The devices are referred herein as soft, flexible, and wearable with advanced power conservation functions and wireless communication capabilities, including being compatible with Bluetooth® enabled systems. Within the system, there is signal processing, signal analysis, and machine learning functionalities that provide a platform for multi-modal sensing for a wide range of physiological and environmental signals that include, but are not limited to: speech, talk time, respiration rate, heart rate, lung volumes, swallowing function, physical activity, sleep quality, movement, eating behaviors. The systems and methods are compatible with use of additional sensors, including one or more of an onboard microphone, pulse oximeter, ECG, and EMG (amongst others).

[0003] Mechano-acoustic signals are known to contain essential information for clinical diagnosis and healthcare applications. Specifically, mechanical waves that propagate through the tissues and fluids of the body as a result of natural physiological activity reveal characteristic signatures of individual events, such as the closure of heart valves, the contraction of skeletal muscles, the vibration of the vocal folds, the cycle of respiration, the movement and sound of scratching, and movement in the gastrointestinal tract.

[0004] Frequencies of these signals can range from a fraction of 1 Hz (for example, respiratory rate) to 2000 Hz (for example, speech), often with low amplitudes beyond hearing threshold. Physiological auscultation typically occurs with analog or digital stethoscopes, in individual procedures conducted during clinical examinations.

[0005] An alternative approach relies on accelerometers in conventional rigid electronic packages, typically strapped physically to the body to provide the necessary mechanical coupling. Research demonstrations include recording of phonocardiography (PCG; sound from the heart), seismocardiography (SCG; vibrations of the chest induced by the beating of the heart), ballistocardiography (BCG; recoil motions associated with reactions to cardiovascular pressure), and sounds associated with respiration.

[0006] In the context of cardiovascular health, these measurements yield important insights that complement those inferred from electrocardiography (ECG). For example, structural defects in heart valves manifest as mechano-acoustic responses and do not appear directly in ECG traces.

[0007] Previously reported digital measurement methods are useful for laboratory and clinical studies but suffer the following disadvantages: (i) their form factors (rigid designs and large size, for example, 150 mm×70 mm×25 mm) limit the choices in mounting locations and prohibit their practical utility as wearable; (ii) their bulk construction involves physical masses that suppress, through inertial effects, subtle motions associated with important physiological events; (iii) their mass densities and moduli are dissimilar from those of the skin, thereby leading to acoustic impedance mismatches with the skin; and (iv) they offer only a single mode of operation, without the ability, for example, to simultaneously capture ECG and PCG/SCG/BCG signals; (iv) their way of communication to the user interface and data transmission are done via wires tethered to the device and the user interface machine; (v) their power management is through wired connection. The devices and methods provided herein address these limitations in the art.

SUMMARY OF THE INVENTION

[0008] Provided herein are methods and devices that provide a telemedicine-type platform, wherein a medical sensor on or implanted in a user provides useful information that can be acted on by a caregiver, such as a medical professional, friend or family member. Not only are the devices and methods useful in diagnostic or therapeutic applications, but can be used for training and rehabilitation. This is reflected in the devices and systems having two-way communication so that information may be sent externally for action to a caregiver and commands received by the medical sensor, including to indicate to a user to take appropriate action, including swallowing, inhalation, exhalation and the like.

[0009] The devices and systems can provide real-time output, such as information useful for novel clinical metrics, novel clinical markers, and beneficial endpoints, thereby improving a user's overall health and well-being. The devices and systems are particularly amenable to utilizing off-site cloud storage and analytics that conveniently, reliably and readily can lead to clinician or caregiver action.

[0010] The special configuration of hardware, software, bidirectional information flow and remote storage and analysis represents a fundamentally improved platform for medical well-being in a relatively unobtrusive and mobile manner untethered to conventional clinical settings (confined to hospitals or controlled environments, for example). In particular, the software, which may be embedded in a chip or processor, either on-board or remote from the devices described herein, and provide much improved sensor performance and clinically-actionable information. Machine learning algorithms are particularly useful for further improving device performance

[0011] Specifically included herein, are the appended claims and any other portions of the specification and drawings.

[0012] In an aspect, provided is a medical sensor comprising: a) an electronic device having a sensor comprising an accelerometer; and b) a bidirectional wireless communication system electronically connected to the electronic device for sending an output signal from the sensor to an external device and receiving commands from an external controller to the electronic device.

[0013] The medical sensor may be wearable, tissue mounted or implantable or in mechanical communication or